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<b>Notice of Allowability</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/667,040	MOLLER, CLAUS SCHMIDT	
	<b>Examiner</b>	<b>Art Unit</b>	
	Theodore J. Stigell	3763	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--**

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 3/12/2007.
2. ☒ The allowed claim(s) is/are 13-15,22-29,36-42 and 44-53.
3. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) ☒ All    b) ☐ Some\*    c) ☐ None    of the:
    1. ☐ Certified copies of the priority documents have been received.
    2. ☒ Certified copies of the priority documents have been received in Application No. 09/882536.
    3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.  
**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS ( as "replacement sheets") must be submitted.
  - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review ( PTO-948) attached
    - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_.
  - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

**Attachment(s)**

- |   |   |
|---|---|
| <ol style="list-style-type: none"> <li>1. <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)</li> <li>2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)</li> <li>3. <input checked="" type="checkbox"/> Information Disclosure Statements (PTO/SB/08),<br/>Paper No./Mail Date <u>See Continuation Sheet</u></li> <li>4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit of Biological Material</li> </ol> | <ol style="list-style-type: none"> <li>5. <input type="checkbox"/> Notice of Informal Patent Application</li> <li>6. <input type="checkbox"/> Interview Summary (PTO-413),<br/>Paper No./Mail Date _____.</li> <li>7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment</li> <li>8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance</li> <li>9. <input type="checkbox"/> Other _____.</li> </ol> |
|---|---|

Continuation of Attachment(s) 3. Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date:  
9/22/2003, 1/26/2006, 3/12/2007, 3/22/2007.

## DETAILED ACTION

### EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Mark Began on 4/9/2007.

The application has been amended as follows:

#### In the Claims

- 1) Please cancel claims 16-21, 30-35, and 43.
- 2) On line 2 of claim 14, please insert --a-- in between ""that" and "portion".
- 3) On line 15 of claim 22, please replace "proximal" with --first--.
- 4) On line 2 of claim 25, please delete "having".
- 5) On line 14 of claim 36, please replace "distal" with --needle--.
- 6) On line 10 of claim 40, please delete "piston".
- 7) On line 10 of claim 50, please delete "but when the device is injecting" and insert --and during the injection of--.

#### In the Specification

In the first line of the amended specification, filed on 3/12/2007, please insert --, now U.S. Pat. No. 6,663,602,-- after "2001".

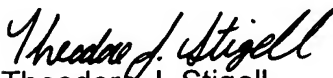
The following is an examiner's statement of reasons for allowance: The prior art made of record did not disclose or suggest a drug delivery device that includes all of the limitations recited in independent claims 13, 22, 36, 40, 47, and 50. Specifically, the prior art did not disclose or suggest a dose dial sleeve (called dose setting drum in claim 40) and a drive sleeve (called tubular element in claim 40) that are releasably coupled together so that these elements rotate together in a dose setting operation to set a dose and decouple from each other in an injection operation allowing the dose dial sleeve to rotate and the drive sleeve to move in a longitudinal direction toward the injection end. The closest pieces of prior art are Burroughs et al. (6,221,046) and Steinfeldt-Jensen et al. (6,235,004). In regards to Burroughs, there is no decoupling between the dose dial sleeve (34) and the drive sleeve (32) and no rotation of the dial sleeve during the injection operation. In regards to Steinfeldt, Figures 15-17 show the closest embodiment to the claimed limitations. However, this device works in a manner that is the complete opposite of the claimed invention in that the drive sleeve (82) and the dose dial sleeve (81) are decoupled during the dose setting operation and coupled together during the injection operation resulting in rotation of both elements.


Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Theodore J. Stigell whose telephone number is 571-272-8759. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

  
Theodore J. Stigell

  
NICHOLAS LUCCHESI  
SUPERVISOR  
ART UNIT 3763